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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,580	07/02/2001	Hansjoerg Reimann	028622/0106	1453

7590

03/22/2005

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EXAMINER
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HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/806,580

Applicant(s)

REIMANN ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-53, 55-60 and 64-66 is/are pending in the application.
- 4a) Of the above claim(s) 57, 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38- 53, 55, 56, 59, 60, and 64- 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to paper filed 15 October 2004.

This action is on claims 38- 53, 55, 56, 59, 60, and 64- 66.

### ***Rejections Maintained***

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 58 and 64- 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for intro recognition of peptide epitopes, does not reasonably provide enablement for inducing immune responses and vaccines against all unstable proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues that Applicant has shown post filing that a T77/C79-149 (fusion of SV40 Tag portion and HBV preS portion) induces immunity, thus this shows enhanced immunity and that the data shown in Ex. 9 can be produced with other antigens. Applicant argues that the article in Immunological Reviews supports that range of vectors and antigens claimed. Applicant concludes that they should be able to claim their invention to provide adequate coverage.

Applicants arguments have been full considered and not found persuasive.

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First, the claims are drawn to any polypeptide that is unstable in a cell. The claims are not limited to known vaccine antigens or antigens that can produce a protective response. The examples referred to by applicant show that immunity is induced with a known antigen (HBV) and both examples referred to by applicant refer to HBV antigens, not a wide range of antigens.

Second, the Tag used in the second polypeptide is not limited to the constructs that have been shown to have the function recited in the claims.

While showing an immune response in mice, Applicant has not shown that these vectors will induce a vaccine immune response in humans with the range of antigens allowed by the claims.

The rejection of record is maintained.

### ***Claim Rejections - 35 USC § 103***

Claims 38- 53, 55, 56, 59, 60, and 64- 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schirmbeck *et al.* (Eur. J. of Immuno., 1997, from IDS) and Fu *et al.*

This invention is drawn to a polynucleotide encoding a fusion protein which is stable in a cell.

Applicant argues that there must be some motivation to combine, there must be a reasonable expectation of success, and that the prior art must teach all the limitations. And argues that Shimbeck[sic] *et al.* does not address the delivery of DNA vaccine delivery of antigen and that TAP deficient individuals would not benefit from a vaccine.

Applicant argues that Fu *et al.* just teaches splicing unrelated antigens into SV40 Tag and that there is no connection to vaccine, immunogenic presentation in vivo hsp association, or other aspects of the claimed invention.

Applicants arguments have been full considered and not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

One of ordinary skill in the art at the time of invention would have known that antigen presentation is useful for inducing an immune response. Schirmbeck *et al.* teach the invention essentially as claimed. Schirmbeck *et al.* teach two constructs (an internal deletion and a C-terminal deletion as recited in the claims) of SV40 Tag associate with hsp73 and allow epitopes on the protein to be processed and recognized by CTLs. One of ordinary skill in the art at the time of invention would have known that peptides and protein fragments are degraded and that the association of hsp73 with Tag is not limited to TAP deficient cells (Schirmbeck *et al.* page 2022, first paragraph of the Discussion). The abstract and Figure 1 of Schirmbeck *et al.* clearly show that epitopes are recognized in TAP plus and TAP deficient cell lines.

Fu *et al.* is used to show that chimeric or fusion proteins can be made with the Tag. Fu *et al.* do not need to teach the elements that are taught in Schirmbeck *et al.*

The rejection is maintained.

**Conclusion**

No claim is allowed.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Myron G. Hill  
Patent Examiner  
17 February 2005



ALI R. SALIMI  
PRIMARY EXAMINER